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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,199	05/18/2000	Rodney Alan Jue	SCIOS.010CP1	9828

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EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/07/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11/13/02

☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-3, 5-11, 13-21, 25, 35-74 is/are pending in the application.

Of the above claim(s) 35-74 is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.

☒ Claim(s) 1-3, 5-11, 13-21, 25 is/are rejected.

☐ Claim(s) is/are objected to.

☒ Claim(s) 1-3, 5-11, 13-21, 25, 35-74 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 17, 18
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Part III: Detailed Office Action

Claims 1-3, 5-11, 13-21 and 25 are under consideration.

The rejection of claims 1-3, 5-11, 13-21 and 25 under 35 U.S.C. § 112, first paragraph is withdrawn in view of applicants' arguments and/or amendments.

5 The new title of the invention is acknowledged.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

10 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-11, 13-21 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 Claim 1 as amended is indefinite for multiple reasons: Due to the deletion of the word "each" in line 2 of the claim, it is not clear whether it is the dimer that comprises the recited amino acid sequence, or alternatively whether each of the monomers comprises said sequence. If the former interpretation is correct, it is not clear what the second monomer *is*. At line 4 of the claim as amended, the claim recites "wherein the Cys of each monomer..."; this lacks sufficient antecedent basis. VEGF comprises six or more Cys residues, and it is not clear to which "*the* Cys" is intended to refer. Further, claim 2 should be amended to refer to *said* Cys residue, for similar reasons. Finally, both claim 1 and claim 14, as amended, are indefinite because it is impossible to 'possess a glycosylation site...that has been eliminated'. One cannot possess that which is no longer there. Claim 14 is additionally indefinite as it is not clear whether one or both monomers retain the Cys at a position corresponding to 116 of SEQ ID NO: 1, nor which Cys is intended by recitation of *the* Cys, as there are multiple Cys residues in VEGF. Claims 15 and 17 as amended are similarly indefinite for recitation of '*the* Cys'.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- 5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10 Claims 1-3, 5-11, 13-21 and 25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tischer et al., U.S. Patent Number 5,194,596, cited by applicants. Applicants argument that the amendments to claims 1 and 14 overcome this rejection have been fully considered but are not deemed persuasive, as said amendments are indefinite, as discussed in the rejection under 35 U.S.C. § 112, second paragraph, above.

15 The Examiner notes that, even if the issues under 35 U.S.C. § 112, second paragraph were resolved, that Tischer would still be held to anticipate the claims, as Tischer discloses the production of the protein in *E. coli*, see for example Column 34. As *E. coli* is incapable of glycosylation, there cannot be said to be a 'glycosylation site' at residues 75-77 for a protein produced in *E. coli*. .
Further, at column 5, Tischer et al. state:

5:7-16 While the native form of the bovine vascular endothelial cell growth factor described herein is apparently glycosylated, there is currently no evidence that glycosylation is
20 essential for biological activity. Accordingly, biologically active nonglycosylated or partially glycosylated forms, which will be produced by prokaryotic or eukaryotic hosts using the expression sequences provided herein, are included within the scope of "vascular endothelial cell growth factor".

In the following paragraph, Tischer et al. identify the site of the glycosylation as being the
25 asparagine residue at residue 74, which corresponds to applicants glycosylation site at 75-77.

Col 7:
37-45 Accordingly, even if that limitation were give weight, the claims would remain anticipated by
Tischer et al.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IT IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be
10 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

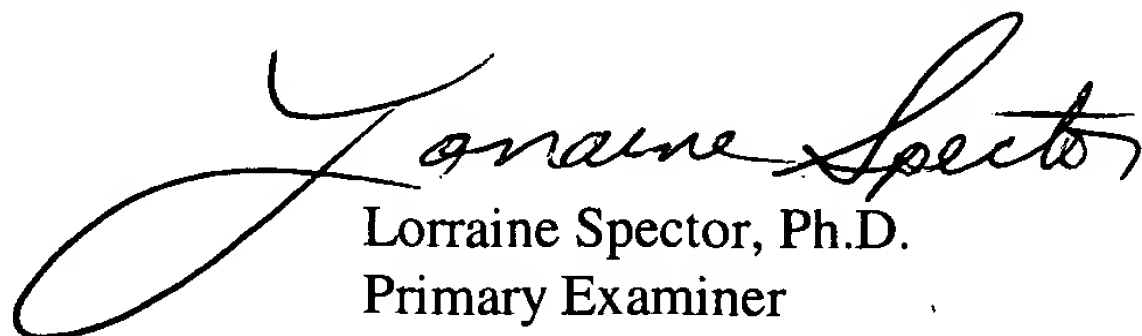
15 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

20 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

25 Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

30 Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

35 
Lorraine Spector, Ph.D.
Primary Examiner

LMS
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2/3/03